HelpNet REACH Workshop: summary of discussions

Time: 1 February 2018, back-to-back with REACH 2018 Stakeholders' Day

The HelpNet REACH Workshop, organised for the HelpNet REACH members and observers, took place on 1 February 2018, in Helsinki. This document summarises the topics discussed during the workshop and the follow-up actions (Annex I).

Session 1 – Opening the REACH Workshop

1.1. Welcome by the Chair

The Chair, Johan NOUWEN, opened the REACH Workshop by welcoming the representatives of the REACH national helpdesks (NHDs) and the observers from Serbia, Turkey, the European Chemical Industry Council (Cefic) and the Only Representative Organisation (ORO) (Annex II – list of participants).

He highlighted the 10 years of good cooperation within the network, and invited all NHDs to continue the good work. He encouraged the helpdesks to spread the news and information available on ECHA's websites, to promote the cloud services, which are particularly addressed to SMEs, and to use the REACH-IT environment made available for them to provide more targeted and helpful advice to companies preparing for the 2018 registration deadline.

1.2. Approval of the draft agenda

The Chair presented the agenda, which included topics relevant for the upcoming REACH registration deadline. He explained that the updated version of the agenda contains more details on the topics addressed in each session, and the lunch hour presentation given by the Chemical Inspection and Regulation Service (CIRS). The agenda was approved without further changes.

1.3. Action points of the REACH Workshop of 29 November 2017

All the action points from the REACH Workshop of 29 November 2017 were closed.

Session 2 – Updates on REACH-IT and Cloud services

2.1 Introduction to REACH-IT training environment

Alexis QUINTANA-SÁINZ (ECHA, Dossier submission & PIC Unit) introduced the REACH-IT[1] training environment that assists industry, Member State competent authorities and ECHA to securely submit and manage data and dossiers.

The presentation covered aspects such as: the main functionalities of REACH-IT; the types of registration dossiers submitted by companies to fulfil their requirements under REACH; the languages available for the help text; how to search for joint submissions; how the tool is used as a communication channel between the three parties to help them coordinate the processing and evaluation of data and dossiers; and how to create and submit a member dossier online.

---

[1] REACH-IT – Registration, Evaluation, Authorisation and Restriction of Chemicals IT tool.

Alexis QUINTANA-SÁINZ advised participants to keep the presentation as a guide on how to use REACH-IT. More information about the tool is available in the REACH-IT section on ECHA's website at: https://echa.europa.eu/support/dossier-submission-tools/reach-it

Key messages: The REACH-IT training environment is offered to NHDs only. The help text within the tool is available in all EU languages. NHDs can submit their questions on IT tools using the contact forms[2] on ECHA's website.

2.2 How to create user account in the REACH-IT training environment

Available support

Eric PAQUAY (ECHA, IT Infrastructure & Support Unit) presented the steps NHDs need to take to log in to ECHA's IT applications, REACH-IT, R4BP[3], ePIC[4] and ECHA Cloud Services. He also showed how to create and manage an ECHA account[5] by using one username and a password, how to reset passwords, and how to edit the access rights of the others users managed under the same legal entity.

Instructions are available in "ECHA Accounts Manual for Industry Users"[6] and the video "Creating an ECHA Account". The manual explains the steps users need to take to access ECHA's IT tools, covering how to create and sign in to ECHA accounts, administer accounts, and create a legal entity. The manual contains mainly screenshots, and no translations are foreseen.

Due to the specificities of this IT environment, the support provided by ECHA will be limited to questions related to the creation of accounts. However, further support on particular cases raised by NHDs and updates from ECHA on the tool will be provided regularly through the monthly phone calls.

Key messages: An ECHA account allows users to log in to ECHA's IT applications (REACH-IT, R4BP, ePIC, and Cloud Services). The REACH-IT training environment will enable HelpNet members to better support industry. NHDs will receive support during the monthly phone calls.

2.3 ECHA Cloud services for SMEs

Mark ROBERTS (ECHA, Computational Assessment & Dissemination Unit) provided an update on ECHA Cloud Services, focusing on the IUCLID cloud services and their benefits.

ECHA Cloud Services is a secure online platform, free of charge, where users can easily access ECHA's IT applications anytime, anywhere. The services currently available include:

- IUCLID Cloud Trial – allowing users to familiarise themselves with a trial version of IUCLID in the cloud, to test, train or work with IUCLID online without having to install the application;
- IUCLID Cloud for SMEs – with additional security-related features, backup and a higher volume of storage than IUCLID Cloud Trial; designed for industry to prepare its dossiers for the last registration deadline; updated regularly with new features, none of them impacting the already submitted information, but making the application more user-friendly.

The IUCLID cloud service allows SMEs, who are non-frequent IUCLID users, to prepare and validate their registration dossiers and to give access to data in their account to consultants. ECHA identified the following most common scenarios as ways of partnership between SMEs

---

and consultants:

- Scenario 1 – Dossier preparation and submission is fully delegated to the consultants.
- Scenario 2 – Dossier preparation is done by the consultants but the dossier is submitted by the SME.
- Scenario 3 – Dossier preparation is done in collaboration by the consultants and the SME and the dossier is submitted by the SME.

One of the key factors that will make the REACH 2018 registration deadline successful is the SME-consultant relationship. More details about the different alternatives SMEs and service providers have for collaboration are available in the webinar[7] held by ECHA and Chemical Watch.

Mark ROBERTS informed participants about the guided dossier preparation tool for the REACH 2018 deadline and about the flow of dossier creation using the guided approach. He also covered IUCLID-related questions[8] received by ECHA from industry. More information is available on ECHA's IUCLID Cloud web page[9] and on ECHA's Youtube channel[10].

In order to address the concerns of industry – raised through the NHDs – about the security of ECHA Cloud Services, the HelpNet correspondents were provided with further details about the architecture security level of the service. Security is at the heart of ECHA Cloud Services, and the main points to note are:

- ECHA's cloud solution is built within ECHA's IT infrastructure. This private cloud does not rely on any public infrastructure. For these reasons, ECHA Cloud Services provides the same infrastructure security level as any other ECHA service, for example, REACH-IT, R4BP and ePIC.

- ECHA Cloud Services implements global measures such as encrypted communications between the client computer and the server, ensuring the confidentiality and integrity of data transferred over the internet.

- ECHA Cloud Services is regularly audited from a security point of view by third parties in order to make sure that all processes to operate the cloud are properly defined and applied, so as to guarantee strictly controlled data management.

- ECHA Cloud Services is regularly tested from a security point of view, taking into account the latest threats identified, to keep the level of protection appropriate. All cloud components are kept up to date with the latest security patches.

- IUCLID Cloud Services can be blocked at any time by the Legal Entity manager in the case that a threat is detected by end users (e.g. compromised credentials) by simply contacting the support desk.

- By design, the IUCLID Cloud solution provides a dedicated IUCLID instance with a dedicated database to store the information. From this point of view, the data of a company is segregated and not stored with data from other companies.

- IUCLID data access is fully controlled by the Legal Entity manager who has subscribed to the IUCLID Cloud Trial service or the IUCLID Cloud for SMEs service, as well as by the user who has been given access to these services by the Legal Entity manager. ECHA employees or Member State competent authorities do not have access to the data stored in the ECHA Cloud service.

Key messages: IUCLID Cloud is secure and aimed at SME users to prepare and submit their registration dossier under REACH for the 2018 deadline.

---

[7] "IUCLID Cloud Best practice for service providers and SMEs" webinar: https://chemicalwatch.com/crmhub/iuclid-webinar.
[8] ECHA Cloud Services Q&As: https://ecs-qa.echa.europa.local/cloud/q-and-a.html.
[9] IUCLID Cloud web page: https://echa.europa.eu/-/getting-to-know-the-iuclid-cloud.
[10] Video tutorials: https://www.youtube.com/playlist?list=PLOPGDACSd6qyDkdXwPua1Fjb5bJksY75k.

Session 3 – Updates from the European Commission and ECHA

3.1 Updates from the European Commission

Temenuzhka POPOVA (European Commission (COM), Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs) provided participants with an update on registration; authorisation; restrictions; nanomaterials; the circular economy[11] strategy and the Stakeholder Conference on 20-21 February; the task in COM's mandate to the Joint Task Force[12] set up between the ECHA Committee for Risk Assessment and the Scientific Committee[13] on Occupational Exposure Limits; and the Regulatory Fitness and Performance Programme[14] (REFIT).

She announced the position of COM regarding the expiry of SIEFs after 1 June 2018 and the phase-in status after 2018 – interpretation of the term "per year" as defined in Article 3(30) of REACH – discussed at the CARACAL-25 meeting. She noted that there is a transitional period embedded in the REACH Regulation, and that COM will publish a legal act clarifying this end date, which in any case will be after the last registration deadline.

The next step will be the presentation of a paper for information in the March CARACAL-26 meeting, with follow-up on consequences of the end of the phase-in scheme, relating to e.g. the use of pre-registrations, Annex III, and data sharing obligations continued after the registration deadline.

On the simplification of the authorisation process, COM is working on the amendment of the following: Annex I for uses in low quantities combined with additional guidance; Annex XIV including an extension of the sunset date for legacy spare parts and preparing measures on applications for authorisation for uses in legacy spare parts; Annex XIV – entries 4 to 7 (endocrine-disrupting properties of phthalates); and reviews of the authorisation for uses of DEHP in recycled soft PVC and of lead chromate pigments.

COM is also discussing whether there is a need for further regulatory action under REACH or under other EU legislation to better protect workers and consumers from skin sensitisers. In this regard, a workshop[15] was organised in December 2017 with Member States, NGOs, scientists and stakeholders. The conclusions of the workshop will be discussed at the next Risk Management Expert Meeting (RiME) on 13-14 February 2018 in Uppsala, Sweden. More information is available in the minutes[16] of that workshop.

The REACH Committee is discussing a possible amendment of the REACH Annexes for nanomaterials, and work is in progress on recommendations for a possible update of the definition of nanomaterial. The European Union Observatory for Nanomaterials (EUON)[17] is under development by ECHA[18]. The main aim of the system is to provide objective and reliable information on the uses and safety of nanomaterials in the EU. COM is actively contributing to the information database and is also participating in the editorial work. EUON should be fully operational in 2019.

---

[11] Circular economy: http://ec.europa.eu/environment/circular-economy/index_en.htm.
[12] Joint Task Force: https://echa.europa.eu/documents/10162/13579/jtf_opinion_task_2_en.pdf/.
[13] Scientific Committee on Occupational Exposure Limits (SCOEL):
http://ec.europa.eu/social/main.jsp?catId=148&intPageId=684&langId=en.
[14] REFIT: https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-and-less-costly_en.
[15] Workshop on regulatory options for skin sensitisers:
https://ec.europa.eu/growth/content/workshop-regulatory-options-skin-sensitisers_en.
[16] Minutes of the Workshop on regulatory options for skin sensitisers:
http://ec.europa.eu/docsroom/documents/27361.
[17] EUON: https://echa.europa.eu/-/eu-observatory-for-nanomaterials-launched.
[18] EUON is a new task for ECHA based on a formal delegation agreement between ECHA and COM signed at the end of 2016. The agreement covers the period up until 2020.

3.2 Updates from ECHA on the implementation of REACH

Borbala ADER (ECHA, Legal Affairs Unit) provided the participants with some statistics on the submissions for registration; briefly explained how the technical completeness check (TCC) and the manual verification are conducted by ECHA; the implementation of the joint submission in REACH-IT; and the actions taken by ECHA to facilitate compliance with the "one substance, one registration" principle.

On data sharing, ECHA has received roughly the expected number of disputes[19]. It was clarified[20] that for disputes submitted according to Article 27 of REACH, a decision is issued by ECHA within 1 month. In disputes submitted according to Article 30 of REACH, decisions are issued within 2.5 months.

Regarding clarification on whether "late-comer fees" apply in a joint submission for companies registering in 2018, it was mentioned that late-comer fees should not be asked from the registrants. Fees can be charged only in relation to the data that the registrants need to submit.

3.3 Directors' Contact Group (DCG) solutions

Laura WALIN (ECHA, Directorate of Registration) provided participants with the latest information on the Directors' Contact Group (DCG)'s proceedings.

In December 2017, the DCG decided to reopen four solutions designed already for the 2010 and 2013 deadlines for companies in exceptional circumstances. The eight solutions on four main issues were opened[21] at ECHA's Stakeholders' Day on 31 January 2018. For historical reasons, the numbering of the issues remained unchanged, and they are the following[22]:

- Issue no. 10 – Completeness of dossiers
- Issue no. 15 – Legal entity (LE) change
- Issue no. 20 – Dependency on the lead registrant
- Issue no. 21 – Substance with no registration intentions

Regarding LE changes, one NHD noted that communication with national enforcement authorities (NEAs) on this subject[23] would be appreciated. Back in 2010, when both CARACAL and the Forum were consulted on the solution, one of the the three Forum members that responded highlighted the fact that harmonised enforcement cannot be guaranteed. Therefore, the solution on the LE changes is to provide a mechanism for companies to be transparent about their situation.

The DCG solutions were further discussed during the World Café session, where more details were provided on the specificities of the scenarios and how ECHA will handle the related requests, and participants had more time to raise their questions and concerns.

Key messages: The following two cut-off dates have to be noted: 31 March 2018 – the date by which companies relying on the DCG issue no. 10.3 should have ordered the laboratory tests; and 24 May 2018 – the date by which companies will need to contact ECHA if they want to benefit from a DCG solution.

---

[19] In 2017, ECHA has received over 80 disputes – nearly four times the number received in 2016. This trend will continue, with 170 disputes expected for 2018.

[20] Information on statistics provided after the meeting (action point 4, Annex II).

[21] DCG issues on ECHA's website:
https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues.

[22] Compilation of the four DCG solutions to be re-activated for the 2018 REACH registration deadline:
https://echa.europa.eu/documents/10162/23556156/171219_dcg_four_solutions_en.pdf/9451fa44-266c-74d5-40d9-8beebd0e5c8b.

[23] Post-meeting note: DCG solutions will be on the agenda of the Forum meeting of 14 March 2018.

3.4 Communication activities

Hanna-Kaisa TORKKELI (ECHA, Communications Unit) presented the latest main communication activities concerning the final registration deadline relevant to NHDs.

She introduced the new four practical examples under the REACH 2018 Roadmap, available in all EU languages: how to decide whether a substance is a polymer or not and how to proceed with the relevant registration; how to gather information to register an inorganic mono-constituent substance and a multi-constituent or a UVCB substance; and confidentiality claims. The first three have already been published[24].

In the REACH 2018 registration context, ECHA asked the HelpNet correspondents to look for non-intentions to register and forward this information to ECHA, in the form of a list of substances that companies have concerns about, as it will help to anticipate certain situations and difficulties around the registration deadline (action point 3, Annex I).

Key message: NHDs are to promote the help available to registrants, e.g. the REACH 2018 web page and the DCG solutions. Also, NHDs should keep an eye on ECHA's website and the ECHA Weekly for last-minute advice, e.g. webinars[25].

Lunch hour presentation

Taking advantage of the visit of the **Chemical Inspection and Regulation Service** (CIRS) to ECHA – organised by the Directorate of Registration and which included a presentation to all ECHA staff – the HelpNet Secretariat invited the HelpNet correspondents to join the lunch hour presentation.

CIRS is a leading product safety and chemical management consulting firm, providing product regulatory compliance services. It is based in China, with subsidiaries and laboratories located in Asia, Europe (Ireland), and the United States.

CIRS provides compliance services such as chemical notifications, global GHS compliance, pesticides and biocides registration, cosmetics and new cosmetic ingredient registration, medical device registration, food and food-related products compliance services, testing, regulatory update monitoring and training services.

Chinese companies are facing challenges similar to those experienced by companies located in Europe, most of the difficulties being related to dossier preparation (e.g. timely submission, data quality), joint submission (e.g. data costs, itemisation of costs, and letters of access), and the typical only representative (OR) problems (e.g. SME verification, payment for additional tests, and documentation of the strictly controlled conditions for intermediates).

Session 4 – World Cafe

4.1 DCG solutions

Margot MAGI (Dossier submission & PIC Unit) and Laura WALIN summarised the discussion on the DCG solutions and the material available in English on ECHA's website. They highlighted the crucial role of NHDs in spreading the news and supporting companies in their countries, in their language.

A common understanding among the participants was that the main issue that may prevent the registrants from submitting the required data by the registration deadline is missing test results (DCG solution 10.3). ECHA explained that in such cases, registrants should provide written justification and documentary evidence that any tests were ordered in a timely manner

---

[24] Practical examples – REACH registration:
https://echa.europa.eu/support/registration/practical-examples
[25] "REACH 2018: Last-minute advice to registrants" webinar on 8 March 2018 (11:00-12:00, Helsinki time): https://echa.europa.eu/-/reach-2018-last-minute-advice-to-registrants

but will be not completed before the deadline. ECHA may then grant the registrant a reasonable time period to complete the dossier, taking into account the need to finalise the missing tests. It was clarified during the discussion that the DCG solution 10.3 indeed applies to Annex VII and VIII data only[26]. In other words, Annex VI information is not in the scope of the solution. ECHA also mentioned that they will monitor the dossier submission process for those companies which have failed the TCC for the first time, to ensure that they will not miss their deadline for completing their dossier.

Finally, the registrants contacting ECHA that find themselves in one of the exceptional situations outlined in the DCG solutions need to be aware that the responsibility for the enforcement of REACH lies exclusively with national authorities, which will eventually react to the registrant's situation in accordance with national REACH implementation legislation.

4.2 Key advice for (first-time) registrants (TCC)

Katalin VALJENTO and Soile NIEMI explained where the technical completeness check (TCC) is located in the registration pipeline; how to use the IUCLID Validation assistant tool before submitting a dossier, to minimise the risk for failures and rejection; the manual verification[27] in TCC; and where the best supporting documents for registrants can be found.

As of 21 June 2016, the automated TCC[28] was complemented with additional manual checks by ECHA staff on certain elements of the registration dossier that cannot be checked automatically. ECHA performs manual verification on about 30 % of both new registrations and updates of existing dossiers. The scope of the manual checks is based on completeness, not quality or compliance, and ECHA does not foresee to modify the TCC before the 2018 registration deadline.

4.3 Key advice for (first-time) registrants (REACH-IT)

Alexis QUINTANA-SÁINZ and István MÁK brainstormed how NHDs can make better use of the REACH-IT training environment, and how NHDs can help companies in replying to basic enquiries about the tool.

Participants mentioned that very few questions on the IT tools are arriving at the NHDs, and that many of them are related to account management. Some NHDs appreciated having available the training environment for further practice at home. Many of them are organising local events providing last-minute advice to companies preparing their registration dossiers. The work done by ECHA to clarify how the IT tools work is expected to pay off.

István MÁK encouraged NHDs to promote to members the online dossier creation tool built into REACH-IT as the easiest way to submit a registration dossier. Also, he suggested that NHDs refer companies to ECHA for enquiries within the Agency's remit.

Conclusions of the REACH Workshop

The Chair gave a summary of the key issues and action points as presented in the conclusions slides and Annex I. He invited participants to provide their feedback on the workshop by replying to the online survey provided after the event. He thanked all HelpNet correspondents, observers and presenters for their active participation in the REACH Workshop.

---

[26] Post meeting note (27 April 2018): In the HelpNet WebEx held on 21 March 2018, ECHA informed the NHDs that the Agency had meanwhile decided to allow companies, upon their request, to apply for the DCG solution 10.3 also for Annex VI data (information for substance identification).
[27] Information on manual verification at completeness check: https://echa.europa.eu/manuals
[28] "Completeness check – preparing a registration dossier that can be successfully submitted" webinar: https://echa.europa.eu/-/completeness-check-preparing-a-registration-dossier-that-can-be-successfully-submitted-to-echa

Annex I – Action points

No.	Action point	Agenda item	Who	Due date	Status
1	Share the link to the minutes of the skin sensitisers preparatory workshop	3.1	COM	15/02/2018	Closed
2	For the Implementing act, consider 'SIEF and data sharing after the registration deadline' and 'Annex III' as additional points for discussions	3.1	COM	7-8/03/2018 (CARACAL-26)	Closed
3	Inform ECHA, and invite industry to do so, on substances which might be not covered by a registration, thus creating a disruption in the supply chain	3.1	NHDs	15/02/2018	Ongoing
4	Provide an update on the number of data-sharing disputes and BoA cases. Information on appeal announcements and decisions is available at: https://echa.europa.eu/about-us/who-we-are/board-of-appeal/announcements	3.2	ECHA	15/02/2018	Closed
5	Clarify whether fees apply for late comers in a joint submission	3.2	ECHA	28/02/2018	Closed

Annex II – List of participants

Country	Name	Surname
Austria	Peter	SCHINDLER
Belgium	Daphné	HOYAUX
Bulgaria	Teodora	BANDAKOVA
Croatia	Jasminka	IVANČEV
Cyprus	Maria	ORPHANOU
Czech Republic	Jan	KOLAR
Denmark	Sidsel	DYEKJÆR
Estonia	Anna	AMELKINA
Finland	Maarit	PRIHA
Finland	Sari	TUHKUNEN
France	Nathalie	HAYAUD
Germany	Suzanne	WIANDT
Hungary	Viktor Péter	NYITRAI
Ireland	Majella	COSGRAVE
Latvia	Amanda	OZOLA
Lithuania	Donata	PIPIRAITE-VALISKIENE
Luxembourg	Laurene	CHOCHOIS
Netherlands	Peter	VAN IERSEL
Norway	Marianne	TVERMYR
Poland	Monika	WASIAK-GROMEK
Portugal	Isabel	LAGINHA
Slovakia	Martina	KUROVÁ
Spain	Laura	ZAMORA NAVAS
Sweden	Helena	Elisabeth KRAMER
Sweden	Jenny	VIRDARSON
United Kingdom	James	LLOYD

Country	Name	Surname
Directorate European Commission	**Name**	**Surname**
DG Growth	Temenuzhka	POPOVA

Observer (candidate country)	Name	Surname
Serbia	Snezana	JOKSIMOVIC
Serbia	Sonja	ROGLIC
Turkey	Eylem Özlem	NALBANTOGLU

Observer (industry association)	Name	Surname
European Chemical Industry Council (Cefic)	Amaya	JANOSI
Only Representative Organisation (ORO)	Kevin	HOBAN

ECHA, directorate/unit	Name	Surname
Support, Forum & HelpNet Secretariat	Johan	NOUWEN
	Ana	VALLEJO CORTE
	Anisa	KASARUHO
	Christina	LOUKOU
	Katarina	CENDIC
	Olena	KRYCHEVSKA
	Patricia	BRILLAS
	Pedro	ROSELLÓ VILARROIG
	Petri	RAUTIMO
	Viorica	NAGHY
	Virve	SIHVOLA
Registration	Laura	WALIN
Dossier submission & PIC	Alexis	QUINTANA-SÁINZ
	István	MÁK

ECHA, directorate/unit	Name	Surname
	Katalin	VALJENTO
	Margot	MAGI
	Soile	NIEMI
Communications	Hanna-Kaisa	TORKKELI
	Maurizio	RONCACCIA
Computational Assessment & Dissemination	Mark	ROBERTS
	Eduardo	VENCESLA JIMENEZ
Legal Affairs	Borbala	ADER
IT Infrastructure & Support	Eric	PAQUAY
Substance ID & Data Sharing	Seyhan	YAZGAN
	Steven	BUCHANAN
Corporate Services	Daniel	NYGARD
	Jekaterina	KUZNECOVA